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| 10/594,776 | 09/29/2006 | Donald A. Tomalia | DNT-7 US | 7146 |
| 50477 7590 05/19/2010 TECHNOLOGY LAW, PLLC 3595 N. SUNSET WAY SANFORD, MI 48657 | | | | |
| EXAMINER | | | | |
| KELLY, ROBERT M | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,776

Applicant(s)

TOMALIA ET AL.

Examiner

ROBERT M. KELLY

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 and 26-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response to restriction requirement and amendment of 2/4/10 is entered.

Claims 1-24 and 26-33 are presently pending and subject to the new restriction requirement and/or species elections below.

To wit, the previous restriction requirement is withdrawn to provide Applicant with a specific group to elect, in a manner this is hopefully more palatable.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 3, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein the core is a simple core.

Group II, claim(s) 4, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein the core is a scaffolding core.

Group III, claim(s) 5, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein the core is a super core.

Group IV, claim(s) 6-8, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein the core is at least one of a Markush group of properties and structures.

Group V, claim(s) 9-11, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein the FF group enables further reaction to join dendrons or reaction with another BR, or "enables a dendron to be used as a core".

Group VI, claim(s) 12-15, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein BR is electro or nucleophilic that can react with the core, an extender, or a terminal functional moiety, and results in a multiplicity of reactive groups for the next generation.

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Group VII, claim(s) 16-18, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein IF is formed from a ring-opening reaction resulting in interior reactive sites.

Group VIII, claim(s) 19-21, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein wherein EX is capable of lengthening the distance for the BR reagent before the next growth generation.

Group IX, claim(s) 22-24, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein wherein TF is any functionally-active moiety that can propagate the dendritic branch to the next generation.

Group X, claim(s) 26, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein the polymer has "enhanced" thermal stability, "improved" chemical stability, and a low polydispersity range.

Group XI, claim(s) 28, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein a carried material is associated with the interior of the dendritic polymer.

Group XII, claim(s) 29-30, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein a carried material which is a pharmaceutically active agent or prodrug is associated with the surface and/or interior of the dendritic polymer.

Group XIII, claim(s) 31-32, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein a carried material which is an agriculturally active agent is associated with the surface and/or interior of the dendritic polymer.

Group XIV, claim(s) 33, drawn to dendritic polymers of formula (I), as defined by Claim 1, wherein the dendritic polymer is a member of a Markush group of 58 members.

Group XV, claim(s) 28, drawn to the dendritic polymers of formula (III), as defined by Claim 2, wherein a carried material is associated with the interior of the dendritic polymer.

Group XVI, claim(s) 29-30, drawn to dendritic polymers of formula (III), as defined by Claim 2, wherein a carried material which is a pharmaceutically active agent or prodrug is associated with the surface and/or interior of the dendritic polymer.

Group XVII, claim(s) 31-32, drawn to dendritic polymers of formula (III), as defined by Claim 2, wherein a carried material which is an agriculturally active agent is associated with the surface and/or interior of the dendritic polymer.

Group XVIII, claim(s) 33, drawn to dendritic polymers of formula (III), as defined by Claim 2, wherein the dendritic polymer is a member of a Markush group of 58 members.

Claim 1 links inventions I-X

Claims 1 and 27 links inventions XI-XIV
Claim 2 links inventions XV-XVIII

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It should be noted that Claim 1 contains three limitations which are incongruent: i.e., "q is independently 0 or an integer from 1 to 2000"; "m is independently 0 or an integer from 1 to 1000"; and "with the proviso that at least one of (EX) or (IF) is present". Hence, it is frustrating proper demonstration of lack of unity, when they are both independently 0, while one must be present. However, for purposes of compact prosecution, it is assumed that the q and m are not independent of each other, but instead, $q + m \geq 1$.

First, Claims 1 and 2 are broken as being drawn to distinct compositions. As noted below, different products are properly restricted under 371 practice. Hence, these claims are broken.

Next, with regard to Inventions I-X, WO 03/033027 to Uchegbu, et al. (supplied by Applicant and hence, not cited herein), teaches several dendrimers anticipating at least claim 3. For example, Applicant's specification defines the term "simple core" in a non-exclusive manner, and hence, the diamino alkanes of Figures 1-4 may be considered the core of each of these, or even the alkanes alone, or even a single carbon atom. The cores have a functionality, because they have hydrogens attached. The branching cells may be the nitrogens or the carbons immediately surrounding them with the nitrogens, or the branches may be considered groups with longer carbons on one site substitution of the nitrogens than another site substitute on the same carbon. The Extenders may be considered the intermediate carbons in the branching chains. The interior functionality may also be provided by the same carbons, as they are functional. The terminal amines and/or other groups bound at the terminal ends may be considered the terminal groups. Hence, the special technical feature is met.

Next, with regard to Inventions XI-XIV, the whole of Uchegbu teaches complexes with DNA, and hence, the special technical feature is met.

Next, with regard to Inventions XV-XVIII, Claim 2 requires simply branches, and terminal moieties, and doesn't even require an FF group. Hence, it is similarly taught by Uchegbu, and hence, because Uchegbu also teaches the complexes with DNA, the technical feature is again met for at least Invention XV.

Moreover, due to the specific distinctions made in each invention, which are not required of any other invention, a search for one would not necessarily have the information to examine and search another invention, and hence, there is a serious burden on the Examiner to search any two inventions together, demonstrating a lack of general inventive concept.

Claim 1 link(s) inventions I-X. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1. Upon the indication

of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1 and 27 link(s) inventions XI-XIV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1 and 27. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 2 link(s) inventions XV-XVIII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 2. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

SPECIES ELECTIONS

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Applicant should choose invention IV:

Applicant should choose a specific genera as in Claim 6, and if Appropriate, Applicant should further choose a specific core of Claims 7 or 8 (i.e., if the choice reads on species of claims 7-8, a specific species election is further required; this is a genera choice, and a species choice according to that genera);

If Applicant should choose invention V:

Applicant should choose a specific genera as disclosed in Claim 9, and a species of that genera as in Claims 10 and/or 11 (i.e., a generic choice in Claim 9 requires a specific subgenera of Claim 10, and, if encompassing Claim 11 species, a single species must be elected).

If Applicant should choose Invention VI:

Applicant should choose a single BR from those of Claims 14-15.

If Applicant should choose Invention VII:

Applicant should choose a single IF group from those of Claims 17-18.

If Applicant should choose Invention VIII:

Applicant should choose a single EX from Claims 20-21.

If Applicant should choose Invention IX:

Applicant should choose a single TF from those listed in Claims 23-24.

If Applicant should choose either Invention XIV or XVIII:

Applicant should choose a single set of defining limitations from the Markush of 58 options in Claim 33.

****It should be noted that any election made, if it is to generic group, of which other embodiments are encompassed by the claims, such will be non-responsive, as the process should not frustrate compact prosecution, but facilitate it. (I.e., if it is generic, and specific embodiments are present that are encompassed, then the election is not to a species.)**

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: All claims are generic for listing a generic species in at least one embodiment.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art,

the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Robert M Kelly/
Primary Examiner, Art Unit 1633